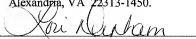


**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicant:	Christopher T. Boyle	Attorney Docket No.:	6006-018
Serial No.:	09/716,146	Examiner:	Cheryl L. Miller
Filed:	November 17, 2000	Art Unit:	3738
Appeal No.		Confirmation No.:	6734
Title:	DEVICE FOR IN VIVO DELIVERY OF BIOACTIVE AGENTS AND METHODS OF MAKING SAME		

**CERTIFICATE OF ELECTRONIC FILING**

I hereby certify that this document (along with any being referred to as enclosed and/or attached) are being filed electronically on this the 24<sup>th</sup> day of March, 2008, addressed to:  
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Lori Dunham

Mail Stop Appeal Brief – Patents  
Commissioner for Patents  
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Alexandria, VA 22313-1440

**NOTIFICATION RE DECISION ON APPEAL**

Dear Sir:

Applicant hereby submits a copy of a Decision on Appeal which was issued by the Board of Patent Appeals and Interferences in Application Serial No. 09/783,633, filed February 14, 2001, and which is currently under appeal as Appeal No. 2008-0216.

This application is related to the instant application by a common assignee.

Respectfully submitted,



J. Peter Paredes  
Reg. No. 57,364

March 24, 2008

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/783,633

02/14/2001

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6006-009

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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

DOCKETED

By: SMC Date: 2-25-08Due: 02/25/2008

NOTIFICATION DATE

DELIVERY MODE

02/25/2008

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* STEVEN R. BAILEY, CHRISTOPHER T. BOYLE,  
DENES MARTON and CHRISTOPHER E. BANAS

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Appeal 2008-0216  
Application 09/783,633  
Technology Center 3700

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Decided: February 21, 2008

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Before DEMETRA J. MILLS, LORA M. GREEN, and  
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 48, 49,  
and 51-66. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

## STATEMENT OF THE CASE

The claims are directed to an implantable sensor device which has structural and sensor elements. According to the Specification, the device can be used “to monitor physical, chemical or electrical parameters of a fluid flow through a body passageway” (Spec. 1: 11-13). The device can be an endoluminal implant, such as a stent, whose mechanical or physical properties are modulated in response to a sensed or monitored parameter (Spec. 1: 16-19). “For example, where the monitored blood flow volume through an endoluminal device is determined to be below physiological norms and/or the blood pressure is determined to be above physiological norms, the stent may be actuated to increase its diameter, such as by superelastic properties of the stent materials” (Spec. 1: 19-22).

Claims 48, 49, and 51-66 are pending (App. Br. 2<sup>1</sup>). Appellants request review of the following rejection:

Claims 48, 49, and 51-66 as anticipated under 35 U.S.C. § 102(b) by Burmeister (EP 0 759 730 B1, published Feb. 10, 1999) (Ans. 3).

Claim 48, which is representative of the appealed subject matter, reads as follows:

48. An implantable sensor device having a plurality of structural elements capable of expanding within an anatomical passageway comprising first and second structural elements where at least some of the plurality of first structural elements

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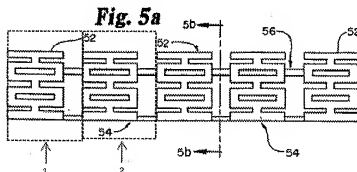
<sup>1</sup> “App. Br.” refers to “Appellant’s Amended Brief on Appeal” filed Jan. 5, 2007.

further comprise at least one first sensor element and where at least some of the plurality of second structural elements further comprise at least one second sensor element, both sensors which selectively detect an energy stimulus and responds to the detection of the energy stimulus by altering the geometry or conformational profile of the device body member.

#### FINDINGS OF FACT ("FF")

##### *The Burmeister patent*

1. Burmeister describes an expandable vascular stent for placement in blood vessels (Burmeister, at col. 1, ll. 6-7).
2. Figure 5a of Burmeister is reproduced below:



3. "Figure 5a . . . shows a stent 50 made up of alternating expandable rings 52 and 54 of austenitic and martensitic alloys, respectively" (Burmeister, at col. 8, ll. 21-23; *see* Ans. 3).
4. "Rings 52 and 54 for example are interconnected by strut members 56 which may be of any material capable of rigidly holding the rings together" (Burmeister, at col. 8, ll. 24-27).

5. The “placement of strut members 56 does not require them to take part in the radial expansion of the stent and they can therefore be of relatively ordinary material such as stainless steel” (Burmeister, at col. 8, ll. 28-32).
6. The expandable rings 52 and 54 are comprised of shape memory alloys (Burmeister, at col. 3, ll. 11-13).
7. Shape memory alloys “are particularly” Ni-Ti [nickel-titanium] alloys (Burmeister, at col. 4, l. 54 to col. 5, l. 3) which change shape in response to temperature (*id.*, at col. 5, ll. 12-22).
8. The stents may be comprised of at least two layers of different Ni-Ti shape memory alloys (Burmeister, at col. 6, l. 20 to col. 7, l. 8; Ans. 5).

*Specification*

9. According to the Specification, the sensor can comprise shape memory materials, such as nickel-titanium alloy (Spec. 9: 24-26; 16: 26-28; 17: 1-5; 26: 4-5, 16-17) which undergo changes in response to energy, such as temperature (Spec. 22, 23: 10-28).

*Claim 48*

10. Claim 48 is directed to an “implantable sensor device having a plurality of structural elements capable of expanding within an anatomical passageway.”
11. The sensor device comprises “first and second structural elements.”
12. Each of the structural elements “further comprise[s]” at least one “sensor element.”

13. The sensor elements “selectively detect an energy stimulus and responds to the detection of the energy stimulus by altering the geometry or conformational profile of the device body member.”

*Application of Burmeister to claim 48*

14. Burmeister’s stent is implantable and expandable (FF 1; Burmeister, at col. 1, ll. 6-7) and thus is “implantable” and “capable of expanding” (FF 10) as required by claim 48.

15. Burmeister’s Figure 5a shows a stent comprising first and second strut members “56” holding the rings of the stent together (FF 4; Burmeister, at col. 8, ll. 24-27)

16. The strut members are structural elements of the stent, satisfying the limitation of claim 48 of “first and second structural elements” (FF 10-11; *see* Ans. 3).

17. *See* particularly dotted line rectangles 1 and 2 shown in Figure 5a.<sup>2</sup>  
Each rectangle contains a structural element (56) of the stent.

18. Each structural element 56 “further comprises” expandable rings 52 and 54 made up of shape memory alloys (FF 3, 6; Burmeister, at col. 8, ll. 21-23; at col. 3, ll. 11-13), such as Ni-Ti alloys (FF 7; Burmeister, at col. 4, l. 54 to col. 5, l. 3), which are the same materials characterized in the Specification

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<sup>2</sup> The dotted line rectangles 1 and 2 are not part of Burmeister’s original figure, but were added for clarity in showing the correspondence between the claimed invention and Burmeister’s stent.



as suitable for its sensor (FF 9; Spec. 9: 24-26; 16: 26-28; 17: 1-5; 26: 4-5, 16-17).

19. The expandable rings 52 and 54 correspond to the “sensor elements” of claim 48 because they are comprised of the same material type described in the Specification as suitable for a sensor element (FF 18). *See* particularly dotted line rectangles 1 and 2 shown in Figure 5a. Each rectangle contains a sensor element (52, 54) of the stent.

20. Thus, Burmeister’s stent comprises 1) a first structural element (56) which further comprises a first sensor element (52) (*see* dotted line rectangle 1 in Fig. 5a (FF 2)); and 2) a second structural element (56) which further comprises a second sensor element (54) (*see* dotted line rectangle 2 in Fig. 5a (FF 2)) – as required by claim 48.

21. The rings 52 and 54 expand in response to a change in temperature (FF 6-7; Burmeister, at col. 5, ll. 12-22) and therefore “selectively detect an energy stimulus” – temperature – and respond “to the detection of the energy stimulus by altering the geometry or conformational profile of the device body member” as in claim 48.

22. All the limitations of the implantable sensor device of claim 48 are described in Burmeister (*see* FF 14-21).

#### ANALYSIS

“A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention.” *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). In

this case, Burmeister describes all the limitations of the “implantable sensor device” (FF 22) of claim 48, including the structural elements (FF 15-17), the sensor elements (FF 18-19), and the capability of expanding in response to detecting a temperature stimulus (FF 14, 21) – and thus anticipates claim 48.

Appellants contend that Burmeister “fails to teach a sensor element that is a distinct element from the structural elements, as recited in claim 48” (App. Br. 4) (emphasis removed).

We do not agree. Figure 5a of Burmeister clearly shows sensor elements 54 and 56 which are separate and distinct from the strut member 56 (see FF 2-5, 20). (The Examiner clearly referred to Figure 5a in the Answer (Ans. 3: 5)). The strut members can be formed of “relatively ordinary material such as stainless steel” (FF 5; Burmeister, at col. 8, ll. 28-32), while the sensor elements are made of shape memory alloys (FF 6; Burmeister, at col. 3, ll. 11-13). Thus, the sensor elements “do not form the entire stent structure” as Appellants contend they do (App. Br. 5).

Appellants argue that Burmeister does not describe a stent comprised of laminated layers (App. Br. 6-7). This argument is not persuasive. Claim 48 does not require the stent to comprise laminate layers of sensor materials. Appellants do not point to any language in claim 48, or identify any other pending claim which contains such a limitation. In any event, Burmeister does, as the Examiner points out (Ans. 5), describe embodiments in which the sensor material is comprised of more than one layer of shape memory alloys (FF 8; Burmeister, at col. 6, l. 20 to col. 7, l. 8).

Appellants also argue that “the Burmeister stent does not qualify as a sensor. In fact, nowhere in *Burmeister* is there a reference to the term ‘sensor’ or a word with an equivalent meaning” (App. Br. 8).

We do not find this argument persuasive. Burmeister uses the same shape alloy materials that Appellants do for their sensor materials (FF 7, 9, 18, 19). Thus, it is not relevant how Burmeister characterizes this portion of its stent since it is comprised of the same material as the claimed sensor element and thus would be reasonably expected to have the same properties.

According to Appellants, “the Examiner’s proposed use of the *Burmeister* stent would render it inoperable and ineffective as a working stent” (App. Br. 9-10).

[T]he *Burmeister* stent is designed to enter into a passive state, whereby the stent’s physical properties theoretically remain constant and are not intended to react/respond to internal conditions of the body, let alone react/respond to an externally applied energy/stimulus, as recited in pending claim 48. Thus, after implantation and initial expansion, the *Burmeister* stent is not designed to undergo any additional conformational changes within the device. Accordingly, the *Burmeister* stent can not function, and is not even intended to function, as a sensor in the manner suggested by the Examiner, *i.e.*, by stimulating the stent with energy to induce conformational changes.

(App. Br. 9).

We do not find this argument to be persuasive. As discussed above, Burmeister’s stent meets all the limitations of the device of claim 48, including the ability to expand in response to a temperature stimulus. While Appellants contend that their device operates differently than Burmeister’s

stent, they have failed to identify any element or limitation in the claim which distinguishes it from Burmeister. Appellants's argument appears to be directed to the *use* of the device of claim 48 – which is not claimed – rather than to the actual device which is claimed.

Appellants further state:

Applicant's stent is formed of at least four elements: a first structural element, a first sensor element, a second structural element, and a second sensor element [footnote omitted]. The sensor elements are specifically configured and designed to be formed of shape memory materials that are different from the shape memory materials used to form the sensor elements. It is this specific configuration, not the use of shape memory material itself, that makes Applicant's stent a sensor."

(Reply Br. 7.)

Burmeister's stent also has four elements: a strut 56 attached to a sensor 52 and a strut 56 attached to a sensor 54 (*see* Figure 5a above of Burmeister, especially dotted line rectangles 1 and 2, respectively; FF 20). Appellants contend that the "specific configuration" of the sensor, not the use of shape memory material distinguishes it from Burmeister, but claim 48 does not require any specific configuration of the sensor other than that the structural element "further comprise" it – a limitation that is clearly met by Burmeister (FF 15-20).

The PTO does not have the ability "to manufacture products or to obtain and compare prior art products." *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977). Thus, once "the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the

burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). Because Appellants use the same material for its sensor that Burmeister employs in its stent, the Examiner has “sound basis for believing that the products of the applicant and the prior art are the same,” shifting the burden to Appellants to provide rebuttal arguments or evidence. Appellants have not shown or provided any evidence that their sensors would perform any differently than the rings 52 and 54 of Burmeister or that the claimed device comprises any structure not present in Burmeister’s stent.

For the foregoing reasons, we affirm the rejection of claim 48. Claims 49 and 51-66 fall with claim 48 because separate reasons for their patentability were not provided. 37 C.F.R. § 41.37(c)(1)(vii).

#### CONCLUSION

We affirm the rejection of claims 48, 49, and 51-66 as directed to subject matter anticipated by prior art.

Appeal 2008-0216  
Application 09/783,633

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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lp